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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,239	04/18/2001	Christof Gysler	88265-4024	1362

28765 7590 08/26/2003

WINSTON & STRAWN  
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EXAMINER

LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 08/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/837,239

Applicant(s)

GYSLER ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4/18/01.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

The USPTO is participating in a search exchange pilot program with the European Patent Office (EPO). As part of the pilot program, the USPTO has received a copy of the Search Report prepared by the EPO on the counterpart EP application for which priority under 35 U.S.C. 119(a) is claimed. The references cited in the EPO Search Report have been considered by the examiner and have been listed on the PTO-892 form. A copy of these references is not being furnished to applicant with this Office action. It will not be necessary for applicant to submit these references in an information disclosure statement.

It is noted that prior to this Office Action, applicant has already submitted an IDS reciting these references. AS such, the references have not been cited on a PTO-892, but are instead considered as present in the IDS.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, drawn to a method of producing a modified, stable industrial-baker's yeast, classified in class 435, subclass 471.
- II. Claims 6-14, drawn to a stable, modified industrial baker's yeast, classified in class 435, subclass 255.1.
- III. Claims 15-18, drawn to a dough composition and a method of producing baked dough products, classified in class 426, subclass 94.

The inventions are distinct, each from the other because of the following reasons:

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Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the yeast strains of group II can be made by a materially different process, such as a recombinant technique or mutagenesis.

Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different effects. The method of group I is directed to the production of yeast strains, which requires different method steps (e.g., the mating of two yeast strains) than the method of group III (e.g., baking the dough). Furthermore, the outcome of the method of group I is the production of a yeast strain, whereas the outcome of the method of group III is the production of dough. Thus, because the different methods have different method steps and outcomes, the methods have different modes of operation and different effects, and are therefore patentably distinct.

Inventions II and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

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§ 806.05(h)). In the instant case the process for using the product can be made using a materially different product, such as a standard baker's yeast strain that has not been modified.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Alan Fanucci on November 21, 2001 a provisional election was made with traverse to prosecute the invention of group II, claims 6-14. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-5 and 15-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 1-18 are pending in the instant application. Claims 1-5 and 15-18 are withdrawn as being drawn to an invention non-elected with traverse. Claims 6-14 are ready for examination in the instant application, and an Office Action on the merits is transmitted herewith.

***Information Disclosure Statement***

The information disclosure statement filed April 18, 2001 has been considered, and a signed and initialed copy of the form PTO-1449 is attached to this Office Action. It is noted that the form PTO-1449 indicated EP 0 441 575 A1 (Document Number AQ) as a reference to be considered. However, it is apparent that applicant intended to indicate the document as EP 0 442 575 A1. This correction has been made on the form PTO-1449 for applicant's convenience.

Applicant has indicated that English translations have been submitted for references AL and AO. However, no translations appear to have accompanied the references. Since these references are in a foreign language, the references have not been considered and are appropriately lined through.

***Drawings***

New corrected drawings are required in this application because of the reasons set forth in the attached Draftsperson's review (form PTO-948). Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that the yeast strains NCIMB 41002, 41032 and 41033 are required to practice the invention. As such, the yeast strains must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 U.S.C. 112, first paragraph, may be satisfied by a deposit of the biological material. In the instant case, the process to generate the strains that is disclosed in the specification does not appear to be repeatable, nor does it appear the strains are readily available to the public.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the instant invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, Applicant may provide assurance of compliance by affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that:

a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon the granting of the patent;

c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and

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e) the deposit will be replaced if it should ever become inviable.

Failure to make one of the preceding indications in response to this Office Action will result in the rejection being maintained in either a second Non-Final or a Final rejection.

It is noted that applicant has indicated in the specification that these strains have been deposited under the Budapest Treaty. However, there is no indication in the application that, upon the granting of a patent, that all restrictions will be irrevocably removed from the strains regarding their availability to the public.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is rejected for the recitation of the term "conventional industrial baker's yeast" as set forth in the last line of the claim. It is unclear what properties of an industrial baker's yeast make the strain conventional, therefore the metes and bounds of the claim are indefinite.

Claim 7 is indefinite for the recitation of the term "sporylated tetraploid zygote" in the second line of the claim. It is unclear if applicant is claiming the tetraploid yeast strain, or a haploid yeast strain that has resulted from the sporulated tetraploid strain. In the interest of compact prosecution, the claim is interpreted as broadly as reasonably possible to indicate that applicant is claiming a haploid yeast strain generated by the sporulation of the tetraploid strain. In addition, the term "sporylated" appears to be misspelled.



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Claim 8 is rejected for the recitation of the term "diploid" in reference to claim 7, which recites that the yeast is tetraploid (see the second line of claim 7). It is unclear how a strain can be both tetraploid and diploid at the same time, since the characteristics of tetraploid and diploid are mutually exclusive.

Claim 9 is rejected for the recitation of the term "lti" in the second line of the claim. It would be remedial to recite the definition of the acronym upon its first appearance in the claim to clearly define what is being referred to.

Claim 11 is rejected for the recitation of the term "higher than the activity of a conventional industrial baker's yeast" in the second line of the claim. The term "higher" is a relative term which renders the claim indefinite. Since it is unclear what constitutes a "conventional industrial baker's yeast," it is unclear what levels of CO<sub>2</sub> production are "higher" than that of a "conventional industrial baker's yeast."

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an

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international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

It is noted that the yeast strain of claim 6 is a product-by-process. However, a review of the method steps indicates that the particular method by which the yeast strain is produced does not confer a specific property to the yeast strain that cannot be conferred by an alternative method (such as a recombinant technique or mutagenesis). As such, the yeast strain is not confined to a yeast strain obtained by the particular method; rather the strain is only confined to a yeast strain having the properties of the end product of the method: a baker's yeast strain having a desirable property resulting from a recessive allele.

Claims 6-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Gysler et al. (US Patent No. 5,399,492; IDS reference AD, Paper #2; see entire document; henceforth Gysler).

Gysler teaches a method of obtaining haploid, diploid and polyploid yeast strains having a desired "lti property", where the yeast strain is used as a baker's yeast strain (see for example column 1, lines 36-57). The process to achieve the "lti property" involves the mutagenesis of a baker's yeast strain, followed by the selection of a yeast strain with the desired property (see for example column 1, lines 47-57). This property, by virtue of the mutagenesis procedure, modifies it relative to a conventional baker's yeast strain. The yeast strain that is obtained can be a haploid strain (see for example column 1, lines 48-50), or polyploid (i.e., tetraploid) strain that

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can be sporulated (see for example column 2, lines 9-20). Thus, Gysler anticipates claims 6-9 of the instant application.

Claims 6-9 are rejected under 35 U.S.C. 102(e) as being anticipated by Takano et al. (US Patent No. 6,410,303; see entire document; henceforth Takano).

Takano teaches the production of haploid, diploid or polyploid baker's yeast strains that have been modified by recombinant techniques (see for example column 2, lines 22-45). Specifically, Takano describes the disruption (e.g., deletion) of the NTH1 gene, which is involved in the breakdown of trehalose in the baker's yeast strains (see for example column 2, lines 35-45). Significantly, the deletion of the NTH1 gene results in the production of a recessive allele, and this recessive allele results in an "Iti property" as set forth in the instant specification (see for example page 7, where applicant indicates that the mutation of the NTH1 gene results in an "Iti property"). Additionally, Takano's definition of a baker's yeast includes haploids, diploids and tetraploids (see for example column 1, lines 57-61). Thus, Takano anticipates claims 6-9 of the instant application.

***Allowable Subject Matter***

No claims are allowable.

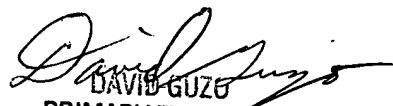
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson  
AU 1636

  
DAVID GUZE  
PRIMARY EXAMINER